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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,965	10/31/2003	Gerrit Reinold Melles	05032-00045	8819
22910	7590	01/12/2006	EXAMINER	
BANNER & WITCOFF, LTD. 28 STATE STREET 28th FLOOR BOSTON, MA 02109-9601			MILLER, CHERYL L	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 01/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/698,965	MELLES, GERRIT REINOLD
	Examiner	Art Unit
	Cheryl Miller	3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 03 October 2005.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 15-17 and 25-28 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-14, 18-24 and 29 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_.

**DETAILED ACTION**

***Election/Restrictions***

Applicant's election with traverse of the species requirement in the reply filed on October 3, 2005 is acknowledged. The traversal is on the ground(s) that a search of all claims is not a burden on the examiner. This is not found persuasive because each method of implantation requires implanting the implant into different locations within the eye, which is a different search for each location of implantation. The examiner is apologetic that the species requirement was not made on the first action on the merits, as it should have been.

The restriction requirement is still deemed proper and is therefore made FINAL. The previous rejection has been withdrawn and the current action is a non-final action.

***Claim Rejections - 35 USC § 101***

Claims 13-14 and 20- 21 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Portions of the body are considered non-statutory subject matter. The above claims recite, an implant, "positioned in the eye", positively claiming the eye as part of the device, being attached to the implant. It is suggested to change the above language to "adapted to be" or "capable of being" positioned in the eye to overcome the rejection. Also, claim 20 positively recited an eye of a vertebrate, which is non-statutory subject matter.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8, 11, 18-24, and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 is a Markush type claim and should contain the language, "selected from the group consisting of" and "and".

Regarding claim 11, the phrase "or the like" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "or the like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

Regarding claim 18, the phrase "for example" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Regarding claims 19-21 and 29, the applicant has changed the scope of the claim, from an implant to an eye and use of an implant or a set, rendering the claim indefinite. The preamble of a dependent claim should be consistent of the preamble of its independent claim, or the dependent claims should be made independent.

Claim 22 recites the limitation "said element" in line 2. There is insufficient antecedent basis for this limitation in the claim. Although and element is recited in the preamble, because it is in the preamble it is considered intended use language, therefore, not yet positively claimed. It is suggested to change "said element" to --an element--. Claims 23-24 depend upon claim 22 and inherit all problems associated with the claim.

Regarding claim 23, the preamble of the claim is incomplete and does not start with a capital letter. Also, the recitation, “preferably being closed with self absorbing suture, glue, or the like” is an alteration of the claim, since the independent claim closes by self-sealing.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 7-9, 12-14, and 18-21 are rejected under 35 U.S.C. 102(e) as being anticipated by site publication [www.stlukeseye.com/Conditions/ForeignBody.asp](http://www.stlukeseye.com/Conditions/ForeignBody.asp) , previously published on 11/23/01 and 08/08/02, see [http://web.archive.org/web/\\*http://www.stlukeseye.com/Conditions/ForeignBody.asp](http://web.archive.org/web/*http://www.stlukeseye.com/Conditions/ForeignBody.asp) . The site discloses a flat element, either a grain of sand or a chip of a nail embedded in the eye, both of which may be considered an “eye implant”. Metal and sand are disclosed by the applicant to be examples of biocompatible elements that are opaque for use with this invention, and such elements are disclosed in the above site. The sand or nail chip disclosed on the site is *capable of* being used as a cosmetic implant and is *capable of* being sterilized (it is noted to the applicant that this is intended use language, and the element disclosed on the site is capable of being used in this manner). The element disclosed on the site has an attachment means (any sharp edge on the sand or nail chip may be considered a means of attachment). The element disclosed in the

site is capable of being implant on or in the conjunctiva (see paragraph under heading treatment). The element is disclosed to be multiple particles (multiple particles of sand).

Claims 1-3, 6-14, and 18-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Young et al. (US 6,656,222 B2, cited previously). Young discloses an eye implant comprising a flat biocompatible element (13) being made of at least partly opaque or light reflecting (portion 21; col.2, lines 4-8, 50-55), such to be visible outside the eye. Young discloses the element (13) to be disc shaped (fig.1, 7) with rounded edges (fig.4, 10). Young discloses an implant made of PMMA (col.4, lines 17-23). Young discloses an implant *capable of* being used as a cosmetic implant and *capable of* being sterilized (it is noted to the applicant that this is intended use language and the implant disclosed is capable of being used in this manner). Young discloses a concave and convex surface (convex and other known shapes, col.4, lines 15-17). Young discloses an attachment means (haptics 15, 17). Young's implant is *capable of* being positioned in or on the conjunctiva of the eye. Young's implant may comprise multiple particles (15, 17, 13, 21; or each protrusion of 21 may be considered a particle). Young's implant inherently comes in a container, since it is an implant for implantation in the body and therefore needs to be provided in a sealed sterilized container as all surgical material is.

Claims 1, 2, 6-10, 12-14, 18-23, and 29 are rejected under 35 U.S.C. 102(e) as being anticipated by Lynch et al. (US 6,783,544 B2). Lynch discloses an eye implant comprising a flat biocompatible element (10; fig.3) at least partly opaque or light reflecting (inherently opaque, since the same materials are used as the applicant has claimed, metals, PMMA; col.6, lines 15-

25), that is visible outside the eye. Lynch discloses a method for implanting an element in the eye comprising providing a partially at least opaque element, providing an opening in the conjunctiva, dissecting part of the conjunctiva, and closing the opening (col.6 line 57-col.7 line 7).

Claims 22-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Pynson et al. (US 5,879,319). Pynson discloses a method for implanting an element in the eye comprising providing a partially at least opaque element (PMMA implant, col.4, lines 17-20; element 1+5), providing an opening in the conjunctiva, dissecting part of the conjunctiva, and closing the opening (fig.6-8, 10).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Young et al. (US 6,656,222 B2, cited previously). Young discloses an eye implant for placement in the eye, however is silent to any specific dimension for the implant. It would have been an obvious matter of design choice to have the dimension claimed, since such a modification would have only involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lynch et al. (US 6,783,544 B2). Lynch discloses a method of implantation of an eye implant in or on the conjunctiva, near the limbus (see fig.4). Lynch is silent however as to what exact distance (how close) the implant is located from the limbus. It would have been obvious to place the implant as close as 2-5 mm to the limbus, since wherein the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pynson et al. (US 5,879,319). Pynson discloses a method of implantation of an eye implant in or on the conjunctiva, near the limbus (see fig.10). Pynson is silent however as to what exact distance (how close) the implant is located from the limbus. It would have been obvious to place the implant as close as 2-5 mm to the limbus, since wherein the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

### ***Conclusion***

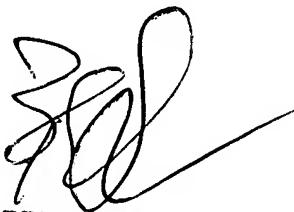
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (571) 272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Cheryl Miller



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PRIMARY EXAMINER